

barbital 10 mg. Caution: For Manufacturing, Processing or Repacking in the preparation of a new drug limited by Federal law to investigational use. \* \* \* Richlyn Laboratories Philadelphia, Pa."

RESULTS OF INVESTIGATION: The *Mannitrau tablets* in the bottles had been repackaged from the bulk drum and relabeled by the consignee. The *Serpenitrite tablets* were intended by the consignee to be repackaged into bottles labeled, in part, "Serpenitrite Rauwolfia Serpent. Po. Rt. 50 mg. Hyoscyamus Pwd. Extract 15 mg. Sodium Nitrite 50 mg. Phenobarbital 10 mg. \* \* \* Use only as directed by a physician. Distributed by William A. Straub Rochester 9, New York."

Neither the Richlyn Laboratories nor William A. Straub had an effective new-drug application for the *Mannitrau tablets* or the *Serpenitrite tablets*.

LIBELED: 2-2-55, W. Dist. N. Y.

CHARGE: 505 (a)—the articles were new drugs within the meaning of the law, and no applications filed pursuant to the law were effective with respect to the articles.

DISPOSITION: 10-28-55. Default—destruction.

**4782. Jel Royale tablets.** (F. D. C. No. 38229. S. No. 9-550 M.)

QUANTITY: 24 100-tablet btls. and 7 500-tablet btls. at Los Angeles, Calif.

SHIPPED: 4-9-55, from San Antonio, Tex., by Howard Harmon.

LABEL IN PART: (Btl.) "Jel Royale Each Tablet Contains 0.5 mg. Queens' Jelly."

ACCOMPANYING LABELING: Brochures entitled "Is This your Fountain of Youth?"

RESULTS OF INVESTIGATION: The brochures were printed locally in Los Angeles, Calif.

LIBELED: 7-27-55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was effective to delay age, restore sexual vigor, and promote growth; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8-18-55. Default—destruction.

**4783. Honey with Royal Jelly.** (F. D. C. No. 38237. S. Nos. 9-553/4 M.)

QUANTITY: 12 cases, 24 12-oz. btls. each, at Los Angeles, Calif., in possession of Halco Corp.

SHIPPED: 4-28-55, from Weslaco, Tex., by Ault Bee Farms.

LABEL IN PART: (Btl.) "100% Pure Bee Ripened Honey \* \* \* Fortified With 57.6 [or "5.76"] Grains Of That Wonder Food Queen's Royal Jelly and 5% Powdered Milk Recommended tablespoon [or "teaspoon"] daily."

ACCOMPANYING LABELING: Circulars entitled "The Queen's Jelly" and "On Honey, Royal Jelly and Natural Foods" and brochures entitled "The Story of 'Royal Jelly' and Peter."

LIBELED: 7-27-55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article when shipped and while held for sale contained false and misleading representations that the

article was effective as a natural remedy for growth, reproduction, rejuvenation, and longevity, as a specific for otherwise incurable maladies, to relieve women during the menopause, to restore normality to the growth of retarded children, to produce a general well-being, to prevent fatigue from prolonged intellectual work, to stimulate the appetite, to stimulate all bodily functions, to cure heart patients, to alleviate suffering from nervous and vascular disorders, to cure Parkinson's disease, and to cure cancer in chickens and prolong the life of pigs, rats, and guinea pigs; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8-15-55. Default—destruction.

**DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE  
HAD BEEN ISSUED**

**4784. Penicillin sodium salt.** (F. D. C. No. 37010. S. No. 63-084 L.)

QUANTITY: 190 vials at Decatur, Ill.

SHIPPED: On an unknown date, from Brooklyn, N. Y.

LABEL IN PART: (Vial) "200,000 Oxford Units Penicillin (Sodium Salt) \* \* \*  
Expiration Date: August - 1947 087040-B."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the labeled potency of penicillin sodium.

LIBELED: 7-20-54, S. Dist. Ill.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, penicillin sodium, the name of which is recognized in the United States Pharmacopeia, an official compendium, and while held for sale its strength differed from the standard set forth in the compendium; 502 (a)—the label statement "200,000 Oxford Units Penicillin (Sodium Salt)" was false and misleading as applied to a product which contained less than the labeled potency; and 502 (l)—the drug purported to be and was represented as a drug composed partly of a kind of penicillin, and it was from a batch with respect to which a certificate or release, as required by regulations, was not in effect.

DISPOSITION: Lincoln Laboratories, Inc., claimant, filed an answer averring that the article was not misbranded while held for sale after shipment in interstate commerce as alleged in the libel, but was held by the claimant for investigational and research purposes only. Subsequently, written interrogatories served upon the claimant by the Government were answered.

The case came on for trial before the court without a jury on 12-6-55, and on 12-16-55, the court, having found that the claimant and the Government had agreed that the product should be destroyed, ordered that the product be released to the claimant for destruction. On 1-5-56, the court entered an order dismissing the libel with prejudice on the grounds that, since the subject matter thereof had been destroyed, all questions in the case had become moot.

**DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS**

**4785. Whole pituitary tablets.** (F. D. C. No. 36371. S. No. 60-144 L.)

QUANTITY: 104,200 tablets in 2 drums at Atlanta, Ga.

SHIPPED: 11-20-53, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Drum) "Special Tablets Enteric SC Brown Code C.D.A.T.  
Lot No.: 8996 Formula contains at time of manufacture: Whole Pituitary  
Po 3 gr. per tablet."